



Northside Hospital & Heart Institute

Kimberly Topper
Food and Drug Administration, CDER
Advisors and Consultants Staff, HFD-21
5600 Fishers Lane
Rockville, Maryland. 20857

Dear Kimberly,

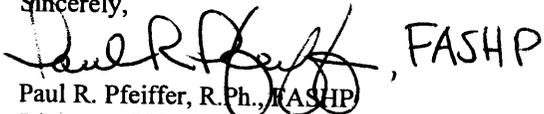
I wish to write in support of the emerging pharmaceutical dosage forms currently used to manage both acute and chronic pain. I have been a Director of Pharmacy in six different hospitals over the previous 28 years and also a Past President of the Florida Society of Health-System Pharmacists. During my tenure as a Pharmacy Director it has been distressing to observe the general inadequacies of pain management. The concerns resulting from unnecessary patient suffering has been aggressively addressed by professional organizations, including the JCAHO. Hospitals, physicians and other healthcare professionals who administer care to these patients have recognized the patient's perception of pain as the fifth vital sign. Of recent, pharmaceutical manufacturers have provided new, innovative and extremely effective alternative dosing formulations for managing pain. Unfortunately at this time those members of our society who seek opiates for illicit purposes have found new and dangerous ways to abuse these products. ***We cannot allow this illicit and irresponsible usage to limit legitimate access by the thousands of patients who need these medications to get through an otherwise painful and suffering day.***

On a personal note, my Mother died of ovarian cancer in 1994. One of my greatest gifts to her was to get her to a professionally enlightened pain management practice at Moffitt Cancer Institute. A team of compassionate professionals assessed her needs and ***her pain was adequately managed with oral long-acting morphine products, until her death. One of my Mother's greatest fears was that of dying a painful death as did my Grandmother, whose death occurred before these medications and our current knowledge was available to her and her physician.***

This past week my Father passed away, having suffered for months with chronic pain resulting from large, open ulcers on his lower legs and ankles. These were a result of aging and insufficient circulation and had become impossible to medically heal. ***The pain associated with these ulcers was generally intolerable until my Father found care through the pain management resources of this Hospital. Oxycontin was used in his care and he was successfully maintained while avoiding the high doses of lessor opiate analgesics containing acetaminophen at near toxic levels.*** These two personal experiences are echoed daily by patients who would otherwise suffer from inadequate pain management.

I encourage our regulatory processes to allow legitimate patient access to these important analgesics while taking the appropriate measures to discourage the illicit usage of these potent medications. We must not limit, hinder or otherwise discourage the evolving practices of pain management that have finally addressed the needs and suffering of our patients in pain.

Sincerely,


Paul R. Pfeiffer, R.Ph., FASHP
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